# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

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| BRENDA RAE SMITH, | * | |
| | * | No. 18-1648V |
| Petitioner, | * | Special Master Christian J. Moran |
| | * | |
| v. | * | |
| | * | Filed: January 12, 2022 |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | entitlement |
| | * | |
| Respondent. | * | |

Brenda Rae Smith, pro se, Sioux Falls, SD;
Christine Becer, United States Dep't of Justice, Washington, DC, for respondent.

**UNPUBLISHED DECISION DENYING COMPENSATION**[1]

Representing herself, Brenda Rae Smith alleged vaccinations she received on November 4, 2015 caused her to develop septic shock, neuropathy, and toxic encephalopathy. Pet., filed Oct. 25, 2018, at pdf 3-4, ¶¶ 2, 6-7. After Ms. Smith filed some medical records, the Secretary reviewed that material and advised that she was not entitled to compensation. Resp't's Rep., filed pursuant to Vaccine Rule 4, Sept. 24, 2020. Ms. Smith has attempted to address the deficiencies the Secretary has identified and has submitted her case for adjudication. For reasons

[1] Because this published decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims's website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). This posting means the decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

that follow, Ms. Smith is not entitled to compensation and her petition is dismissed.

## I. Procedural History

Ms. Smith filed her petition on October 25, 2018, and with her petition, she included approximately 50 pages of medical records. See Pet., filed Oct. 25, 2018, at pdf 11-56. Ms. Smith neither assigned exhibit numbers to the material nor paginated the document.[2] Ms. Smith submitted a compact disc to the Clerk's Office on December 19, 2018 and February 8, 2019. These compact discs duplicate each other and contain exhibits 1 through 4.

The Secretary determined that Ms. Smith had not filed all records and requested that she obtain them. Resp't's Status Rep., filed Apr. 18, 2019. Accordingly, Ms. Smith was directed to file additional medical records. Order, issued Apr. 25, 2019.

Ms. Smith submitted USB drives on July 30 and August 22, 2019. These USB drives again duplicate themselves and contain exhibit 5. The Secretary responded, noting that some medical records were still missing. Resp't's Status Rep., filed Sept. 20, 2019.

Ms. Smith submitted more records on February 3 and February 14, 2020. Exhibits 6 and 7. She submitted more records on April 20, 2020, which are also labeled Exhibit 1. Ms. Smith filed exhibit 8 on July 29, 2020. At this point, another status conference was held, during which the Secretary stated that he could assess the available information.

The Secretary recommended that compensation be denied. Resp't's Rep., filed Sept. 24, 2020. The Secretary appeared to parse the petition thoroughly to understand Ms. Smith's claims. The Secretary also presented a detailed account of Ms. Smith's medical history, citing evidence for each assertion.

In the ensuing status conference, which was recorded, the parties discussed the Secretary's position that Ms. Smith's claims lacked supporting evidence. After the status conference, the Secretary again listed missing medical records and requested them. Resp't's Status Rep., filed Oct. 16, 2020.

[2] The first 2 pages appear to be a sample petition, which does not contain assertions relevant to Ms. Smith's case.

Ms. Smith filed 99 more pages of medical records on December 21, 2020. Exhibits 9-17. Although she may have differentiated portions into exhibits 9-17, the labeling of specific exhibits is not clear. Ms. Smith more clearly identified exhibits 18 and 19, which she included with a March 17, 2021 response to the Secretary's report. Pet'r's Status Rep., filed Mar. 17, 2021, at pdf 6-14. Following Ms. Smith's submission, another recorded status conference occurred on May 4, 2021.

In the May 4, 2021 status conference, Ms. Smith maintained that the evidence demonstrated that she was entitled to compensation. When asked whether she wanted to retain an expert, Ms. Smith stated that hiring doctors costs money and she was not working full-time. In any event, according to Ms. Smith, she deemed her case worthy of compensation despite not having an expert.

After the status conference, respondent repeated a request for records. Resp't's Status Rep., filed May 12, 2021. In response, Ms. Smith filed approximately 40 more pages of material consisting of argument and medical records. See Pet'r's Status Rep., filed July 1, 2021. Ms. Smith argued that she experienced an on-Table injury in the period after receiving vaccination and therefore vaccine-causation is presumed. Id. at pdf 2. She asserted that the medical records contain no evidence that an infection was the cause of her injuries. Id. She further maintained that her injuries have persisted for 6 years since her vaccination in November 2015. Id. at pdf 1. With the submission of Ms. Smith's updated medical records and argument, this case is ready for adjudication.

## II. Standards for Determining Facts

Petitioners are required to establish their cases by a preponderance of the evidence. 42 U.S.C. § 300aa-13(a)(1). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for finding facts in the Vaccine Program begins with analyzing the medical records, which are required to be filed with the petition. 42 U.S.C. § 300aa-11(c)(2). Medical records that are created contemporaneously with the events they describe are presumed to be accurate. Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, medical records

may not always list all problems a person is experiencing. See Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021).

Pursuant to these standards for determining when events did or did not happen, the undersigned finds how the evidence preponderates. In setting forth the findings, the undersigned also cites to the primary evidence that is the basis for the finding. The undersigned recognizes that not all evidence is entirely consistent with these findings. See Doe 11 v. Sec'y of Health & Hum. Servs., 601 F.3d 1349, 1355 (Fed. Cir. 2010) (ruling that the special master's fact-finding was not arbitrary despite some contrary evidence).

## III. Findings of Facts

Events in Ms. Smith's life can be divided into 3 periods. The first period is Ms. Smith's health before she was vaccinated. The next concerns two hospitalizations in November 2015 during which she was vaccinated. The last period is from December 2015 through the most recently submitted medical records.

### A. Health Before Vaccination

Ms. Smith was 46 years old and had a past medical history significant for conditions including attention deficit hyperactivity disorder (ADHD), depression, gastroesophageal reflux disease, anxiety, post-traumatic stress disorder (PTSD), and anemia. Exhibit 1 at pdf 11, 17; exhibit 5 at pdf 747. Ms. Smith was also hospitalized several times for anxiety-related issues. Exhibit 5 at pdf 1199 (hospitalization on May 3, 2008); id. at pdf 1161 (hospitalization on October 22, 2010); id. at pdf 915 (hospitalization from August 3-7, 2015).

On October 20, 2015, Ms. Smith underwent an elective paraesophageal hernia repair. Id. at pdf 756.

### B. Hospitalizations in November 2015, Including Vaccination

During November 2015, Ms. Smith was hospitalized twice. She received a flu vaccine on November 4, 2015 during her hospitalization.

#### 1. Admission on November 2, 2015

On November 2, 2015, Ms. Smith presented to Emergency Department ("ED") at Avera McKennan Hospital and University Health Center, complaining of shortness of breath and anxiety. Exhibit 1 at pdf 11. On arrival, she was

tachycardic with decreased blood pressure. Id. A chest X-ray showed "a tension pneumothorax with significant hydropneumothorax on the left [lung]." Id. at pdf 11-13. Ms. Smith underwent a left chest needle decompression, which removed approximately 1400 to 1600 mL of pus. Id. at pdf 13, 15. A CT scan revealed upper abdominal gas and a large fluid collection in the lesser sac, as well as an enlarged liver, hepatic steatosis, and a laceration along Ms. Smith's spleen. Id. at pdf 15-16, 187-88. The attending physician determined that Ms. Smith's condition was secondary to the hiatal hernia/paraespohageal dissection. Id. at pdf 16. Ms. Smith had difficulty talking and was taken to the ICU for emergent intubation. Id. at pdf 15-16. She was placed on IV sedation, after which her blood pressure dramatically improved. Id. at pdf 16.

The next day, Ms. Smith stabilized and came off ventilator support. Exhibit 1 at pdf 34. Ms. Smith was able to ambulate with assistance, but she was confused, impulsive, and agitated at times. Id. at pdf 647.

On November 4, 2015, Ms. Smith received a flu vaccine in her right deltoid. Id. at pdf 260.[3] Ms. Smith alleges that this vaccination caused a plethora of health problems.

On November 5, 2015, she had a transfusion for her anemia. Id. at pdf 40. Her blood cultures and cultures of the pleural fluid were noted to be positive for Beta Hemolytic Streptococcus. Id. at pdf 42.

On November 6, 2015, Ms. Smith had a repeat chest CT scan, which revealed an increase in pleural fluid and new, moderate pleural effusion. Id. at pdf 193. An abdomen-pelvic CT scan revealed pelvic fluid. Id. at pdf 194. On November 7, 2015, Ms. Smith had a pigtail drain placed for the pleural effusion, as well as CT-guided drainage for the purulent appearing pelvic fluid. Id. at pdf 195, 197. Ms. Smith showed improvement the following day. Id. at pdf 51.

[3] In the litigation, Ms. Smith often referenced a document listing more than a dozen vaccines. See exhibits 9-17, filed Dec. 21, 2020, at pdf 5; exhibit 19 at pdf 14 (duplicate); Pet., filed Oct. 25, 2018, at pdf 16; Pet'r's Status Rep., filed July 1, 2021, at pdf 16. However, this list does not show that Ms. Smith received vaccines other than the flu vaccine. Ms. Smith has exhausted efforts to establish that she received vaccines other than the flu vaccine in November 2015. See Pet'r's Status Rep., filed July 1, 2021, at pdf 1.

On November 11, 2015, seven days after receiving the flu vaccination in her right arm, Ms. Smith complained of right thigh pain. Exhibit 1 at pdf 649. She told the nurse that "she thinks it is from an injection," and that she "believes that a needle was 'stuck' in her." Id. at pdf 649-50. The nurse assured Ms. Smith that she did not have a needle in her thigh. Id. at pdf 650. No other reports of leg pain appear in the extensive records from this hospitalization.

Ms. Smith was discharged on November 14, 2015. Id. at pdf 8. Her discharge diagnoses were left chest empyema, left chest pneumothorax, intra-abdominal abscess, leukocytosis, and anemia. Id. She was able to ambulate independently, her vital signs were stable, and she transitioned to oral antibiotics. Id.

2. Admission on November 17, 2015

Three days later, on November 17, 2015, Ms. Smith was brought back to the Avera McKennan Hospital's ED by EMS after she was found unresponsive. Exhibit 2 at pdf 36. There was a report of an empty narcotic pain medication bottle next to her when she was found. Id.[4] She was intubated at the scene and given Narcan. Id. The attending ED physician noted that Ms. Smith's condition was consistent with an opiate overdose. Id. at pdf 37. A chest X-ray showed "significant white out of the left lung field," while a CT scan of the chest, abdomen, and pelvis showed "bilateral pleural effusions with a left upper and lower lobe consolidation and multiple loculated fluid collections in the abdomen." Id. Ms. Smith was admitted to the ICU for "further evaluation of this complicated medical condition involving opiate overdose with concern for developing sepsis secondary to this left-sided empyema and intraabdominal abscess." Id. Possible etiologies for her condition included "septic encephalopathy with sources of empyema, aspiration pneumonia, or abdominal abscess or overdose/toxic ingestion." Id. at pdf 39.

Ms. Smith was treated for her infections and was discharged on November 30, 2015. Exhibit 2 at pdf 26. Her diagnoses at discharge included toxic encephalopathy, sepsis, abdominal abscess, anxiety, major depressive disorder, acute renal failure, and streptococcal bacteremia. Id. She was advised to follow up

[4] This was later noted as liquid oxycodone. Exhibit 2 at pdf 27. However, a toxicology screen was only positive for benzodiazepines. Id. Ms. Smith emphasized that a toxicology screen was negative for opiates. Pet'r's Status Rep., filed July 1, 2021, at pdf 2; see also id. at pdf 38; exhibit 18 at pdf 8.

with her primary care provider in one week. Id. at pdf 28. One medication at discharge was gabapentin. See Pet'r's Status Rep., filed July 1, 2021, at pdf 37.

Ms. Smith asserts that the cost of medical treatment in November 2015 exceeded $200,000. This debt, in turn, affected Ms. Smith's ability to seek additional medical care. See Pet'r's Status Rep., filed July 1, 2021.

### C. Events After November 2015

On December 10, 2015, Ms. Smith went to a clinic reporting sharp abdominal pains and shortness of breath. Exhibits 9-17, filed Dec. 21, 2020, at pdf 6. The clinic directed Ms. Smith to the emergency department. Id. at pdf 8.

In the emergency department, Ms. Smith complained of chest discomfort and abdominal pain. Exhibit 4 at pdf 3. Her past medical history included toxic encephalitis and sepsis. Id.; exhibits 9-17 at pdf 11 (duplicate); Pet'r's Status Rep., filed July 1, 2021, at pdf 38 (duplicate).[5] Lab testing and a CT scan of the chest, abdomen, and pelvis did not reveal any acute findings, and she was not admitted. Exhibit 4 at pdf 4, 16-17.

#### 1. 2016

On January 22, 2016, a CT scan of Ms. Smith's chest, abdomen, and pelvis CT was performed, and showed "[r]esolution of left chest atelectasis and abdominal fluid collections," as well as an abnormal uterus, which was similar to several previous examinations. Exhibit 5 at pdf 1233.

On February 12, 2016, a doctor from Sanford Physical Medicine and Rehabilitation Clinic, (Dr. Susan Assam) referred Ms. Smith for outpatient speech and language therapy. Exhibit 8 at 59; see also exhibit 19 at pdf 13; Pet'r's Status Rep., filed July 1, 2021, at pdf 20. It appears likely that Dr. Assam's office created additional records, but these unfortunately have not been filed.[6] For example, the record does not contain any clinical notes. Regardless of what might be missing, the evidence shows that Ms. Smith's active problems from that date include

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[5] Ms. Smith's medical records refer to both toxic encephalitis and toxic encephalopathy. See, e.g., exhibit 2 at pdf 26; exhibit 4 at pdf 3; exhibit 8 at 13; exhibits 9-17 at pdf 11; Pet'r's Status Rep., filed July 1, 2021, at pdf 38.

[6] Ms. Smith maintained that no other records from Dr. Assam are available. Pet'r's Status Rep., filed July 1, 2021, at pdf 1.

anxiety, renal failure, impaired cognition, lethargy, sepsis, and streptococcal bacteremia. Exhibit 8 at 62-63. No allergies or adverse reactions are listed. Id. at 63.[7] The associated diagnosis listed on the referral is "encephalopathy due to infection." Id. at 66.[8] Ms. Smith emphasizes the ICD-10 diagnostic codes associated with her encephalopathy diagnosis at her February 12, 2016 appointment with Dr. Assam. See exhibits 9-17 at pdf 44; Pet'r's Status Rep., filed July 1, 2021, at pdf 17-18, 20.[9]

A page from a February 16, 2016 record signed by Dr. Assam reflects a plan that included an X-ray of Ms. Smith's lumbar spine and evaluation of right leg pain.[10] Exhibit 8 at 60.

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[7] Records show that the flu vaccine was added as an allergy in Ms. Smith's chart on March 28, 2017, and the MMR vaccine was added on December 29, 2019. Exhibit 8 at 89. There is no information identifying who added these to Ms. Smith's record, or the basis for these additions.

[8] In addition to the typed notation of "encephalitis," there is handwriting saying "encepillitis," as well as other writing that is mostly illegible. Exhibit 8 at 59. Who wrote on this document is not readily apparent.

[9] Ms. Smith's emphasis on the diagnostic codes associated with her encephalopathy diagnosis might be to show that she is entitled to a presumption of causation for an on-Table claim. See Pet'r's Status Rep., filed July 1, 2021, at pdf 2. The Vaccine Injury Table does not associate the flu vaccine with encephalopathy.

[10] Except for a mention of right thigh pain during Ms. Smith's hospital visit on November 11, 2015, exhibit 1 at pdf 649-50, this is the first dated reference to leg pain in the record. However, contained within an assortment of records filed on July 29, 2020, is a one-page portion of an undated medical note by an unidentified individual that indicates that Ms. Smith had "some right leg pain for which she is not sure whether she fell," specifying that the leg pain occurred "mostly at night." See exhibit 8 at 13. Because the note indicates that Ms. Smith "has not had any imaging of her back," it likely that this note is part of a record created at or around the time of the February 2016 visits with Dr. Assam. Id. The impression by the document's author was that Ms. Smith had encephalopathy due to infection (the same diagnosis on Dr. Assam's referral), and mid-line low back pain with sciatica, presence unspecified. Id. at 13, 59. The record also states that

On February 23, 2016, Ms. Smith presented to internal medicine specialist Dr. Lorraine Huet-Holm at Sanford Women's Internal Medicine Clinic to establish care. Exhibit 7 at 33; see also Pet'r's Status Rep., filed July 1, 2021, at pdf 4. The following issues were addressed at the visit: history of sepsis; history of renal failure; and right leg paresthesias. Exhibit 7 at 33. The record from this encounter notes that Ms. Smith and Dr. Huet-Holm "discussed the possibility of doing [a] MRI of [Ms. Smith's] lumbar spine and nerve condition studies to further evaluate [her] right leg pain and numbness." Id. Other than recording Ms. Smith's vital signs, the record does not provide any further clinical information from this visit. Id.

On March 3, 2016, Ms. Smith returned to Dr. Huet-Holm for complaints of cold extremities, dizziness, and fatigue. Id. at 35; exhibit 8 at 115-16; see also Pet'r's Status Rep., filed July 1, 2021, at pdf 5. During the visit, Dr. Huet-Holm also addressed Ms. Smith's radicular leg pain, speech delay, elevated alkaline phosphatase level, ADHD, and anxiety. Exhibit 8 at 115. The medical records again fail to provide any relevant clinical information about these problems. Id. at 115-16. Dr. Huet-Holm informed Ms. Smith that the neurology office would call her directly, and a nurse would call to set up a MRI. Id. at 115. Ms. Smith had a lumbar spine MRI for radicular leg pain the following day; the results showed "minimal disk desiccation at L3-4 and L4-5," and an "[i]ncidental tiny perineural cyst within the low sacral canal." Exhibit 7 at 3.

On March 21, 2016, Ms. Smith presented to the ED for complaints of a rash and nerve pain. Exhibit 7 at 29. She was diagnosed with insomnia and a skin rash. Id. The discharge information included patient information about insomnia and non-specific skin rash, but no clinical information was provided. Id. at 29-32.

On October 5, 2016, Ms. Smith presented to Dr. Huet-Holm for medication management, pain, and pleurisy. Exhibit 7 at 6; exhibit 8 at 95 (duplicate); exhibits 9-17 at pdf 41 (duplicate). The issues addressed during the visit were Ms. Smith's history of sepsis, ADHD, prophylactic antibiotic, and right leg paresthesias. Id. The medical record provided does not provide any relevant clinical information. Id.

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Ms. Smith was scheduled to see a Dr. Dehaan for a medical evaluation; however, to date, no records from this individual have been filed. Id. at 13.

2. 2017

On March 28, 2017, Ms. Smith presented to family medicine specialist Dr. Robert Seidel for respiratory complaints. Exhibit 8 at 117. She had a mild cough, head congestion, and body aches. Id. Dr. Seidel diagnosed her with viral upper respiratory infection. Id. This is the only medical record filed from 2017.

3. 2018

On January 9, 2018, Ms. Smith presented to Dr. Scott Ecklund, a family medicine physician. Exhibit 8 at 106. Ms. Smith reported several concerns to Dr. Ecklund, including that she had "severe sepsis in October 2015 after she had a hernia repair and her spleen was lacerated." Id. She told Dr. Ecklund that she was hospitalized for two weeks, and "has had fatigue off and on since that time." Id. She felt that her fatigue "flared 'overwhelmingly' on December 19, 2017," and she wanted to find the cause of her fatigue. Id. Ms. Smith also reported that she had neuropathy of the right leg for which she occasionally takes gabapentin. Id. at 106-07. On exam, her cranial nerves were intact, her deep tendon reflexes were 2+ and symmetrical bilaterally, and her strength and sensory exam were normal. Id. at 107. Dr. Ecklund's record lists the influenza vaccine under "allergies," after which "encephalitis and neuropathy" appear as the reported reactions. Id. at 106. There is no discussion about this notation or how it came to appear in the record.

Ms. Smith returned to Dr. Ecklund on May 1, 2018, for her ADHD, anxiety and depression, insomnia, and neuropathy. Id. at 3. Regarding the neuropathy, Ms. Smith informed Dr. Ecklund that she has "had this problem in her right leg ever since she had her encephalitis." Id.; see also exhibits 9-17 at pdf 12; Pet'r's Status Rep., filed July 1, 2021, at pdf 29. The record contains no explanation as to why Dr. Ecklund believed that Ms. Smith had encephalitis.[11] Ms. Smith's neurologic exam was normal. Exhibit 8 at 4.

On May 2, 2018, Ms. Smith had an initial physical therapy evaluation. She told the therapist that she

> had a hiatial hernia operation done on Oct 20th, 2015 but her spleen was lacerated but she then became [septic], collapsed lung, collapsed diaphragm, and left

[11] Given that the reference to encephalitis appears in the subjective section of the medical record, it is likely that Ms. Smith reported this diagnosis to Dr. Ecklund. See exhibit 8 at 3.

> lung issues. She developed multiple abscesses in her entire body. She said she was given multiple immunizations while she was septic. She said her right leg neuropathy started 7 days after this surgery. She was discharged from the hospital a few days later. Her symptoms did not improve. Her immunizations appeared to have effected issues with walking and she fell at home. Her sepsis was not cleared and she went into septic shock and developed kidney failure and was re-admitted to the hospital November 17th, 2015. She was found to have major nerve damages and was in the hospital and was transferred to the brain injury institute for 2 weeks.

Exhibit 6 at 38. Her diagnoses from this visit were unspecified polyneuropathy, low back pain, pain in the thoracic spine, cervicalgia, other muscle spasm, and generalized muscle weakness. Id.

Ms. Smith returned to Dr. Ecklund on June 25, 2018, for an evaluation and treatment for right ear pain, ADHD, insomnia, and chronic right lower back pain. Exhibit 8 at 99; see also exhibits 9-17 at pdf 19. She mentioned that she saw a rehab doctor "who felt [that] her encephalopathy was due to a vaccine," but was "[n]ot sure which one caused it." Id. Ms. Smith stated that "[s]ince that time, she has had persistent trouble with speech," and she felt that "everything has changed." Id. She also stated that she was "pursuing legal avenues regarding the potential vaccine cause of her encephalopathy." Id. Dr. Ecklund noted that Ms. Smith continued to have pain in her right lower back down to the right knee "that has been [present] since the encephalopathy." Id.

Ms. Smith reported that she had "retained an attorney and [was] looking at working with him to get her records together and see if there [was] a vaccine liability fund that [was] available to help her financially as she continue[d] to work on her rehab for this problem." Exhibit 8 at 100.

On August 8, 2018, Ms. Smith received a massage at Massage Envy. Exhibits 9-17 at pdf 59. Her service provider noted that her health history included chronic pain. Id. Ms. Smith appears to have told her service provider to avoid her upper legs because they were painful to massage. See id. On August 30, 2018, Ms. Smith returned to Massage Envy for a deep tissue massage. Id. at pdf 60.

4. 2019

On January 4, 2019, Ms. Smith went to Massage Envy. Id. at pdf 61. Her service provider noted that there were no specific focus areas and that Ms. Smith requested lighter pressure. Id. On March 8, 2019, Ms. Smith again received a massage. Id. at pdf 62. Her service provider wrote that Ms. Smith's erectors were tight and that she had nerve damage on her right side from her quadriceps to her iliac crest. Id. At her next appointment on April 10, 2019, her service provider noted that her right side above her iliac crest was tight. Id. at pdf 63. Ms. Smith returned to Massage Envy in May 2019, June 2019, August 2019, September 2019, and November 2019. Id. at pdf 64-68. At her November 11, 2019 appointment, her service provider focused on her lower back and glutes. Id. at pdf 68.

Ms. Smith saw Dr. Ecklund again on May 6, 2019. Exhibit 8 at 10; exhibits 9-17 at pdf 24. Dr. Ecklund noted that Ms. Smith "had severe sepsis/encephalopathy in October 2015 after she had a hernia repair and her spleen was lacerated," and that she has had severe fatigue symptoms, ongoing neuropathy, and severe pain in her right leg since that time. Exhibit 8 at 10; see also exhibits 9-17 at pdf 24. On exam, her reflexes and strength were within normal limits, and her sensory exam was normal. Exhibit 8 at 11. Dr. Ecklund diagnosed Ms. Smith with chronic pain syndrome. Id.

5. 2020

On March 18, 2020, Dr. Ecklund completed paperwork in support of a disability application for Ms. Smith. Exhibit 1 (second) at 5-8. He lists "right sided neuropathy" and PTSD as her impairment. Id. at 5.

On August 1, 2020, Ms. Smith saw Dr. Chau Huynh, an acupuncturist, for right lumbar pain. Exhibits 9-17 at pdf 69. Dr. Huynh reported that Ms. Smith was tight along her iliac crest. Id. He also noted that she had a weak pulse, water accumulation, and blood stagnation. Id. He recommended more acupuncture, cupping therapy, and infrared lamp therapy. Id.

Ms. Smith returned to Dr. Huynh on August 5, 2020, complaining of pain on her right side and bloating due to water accumulation. Id. at pdf 71. Dr. Huynh noted that Ms. Smith was in good general health and had tightness in her right lumbar. Id.

Ms. Smith saw Dr. Huynh again in August 2020, September 2020, and October 2020 to address complaints of insomnia, lumbar pain, and lower back pain. Id. at pdf 73-98. She reported improvement in her insomnia, lumbar pain,

and lower back during these visits. See, e.g., id. at pdf 83 (Ms. Smith reported improvement in her lower back pain during her September 12, 2020 visit); id. at pdf 87 (Ms. Smith told Dr. Huynh that her quality of sleep was getting better during her September 16, 2020 visit); id. at pdf 89 (Ms. Smith reported on September 30, 2020 that she could work throughout the day without her back bothering her); id. at pdf 93 (Ms. Smith told Dr. Huynh on October 21, 2020 that she could "stretch her back much better than before" and that "her sleeping [was] good"). These are the most recent medical records.

## IV. Standards for Adjudication

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing the special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with the dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

Ms. Smith alleges, by implication, that she suffered an off-Table injury.[12] For an off-Table injury case, the Federal Circuit has defined the elements of a petitioner's case. Petitioners bear a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of

[12] The Vaccine Injury Table associates the flu vaccine with anaphylaxis, a shoulder injury, syncope, and Guillain-Barre syndrome. XIV. However, Ms. Smith has not alleged that she suffered any of these injuries. Moreover, if Ms. Smith had made any allegation regarding table injury, the medical records would not support any assertion.

cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

To find vaccine-causation, a petitioner must substantiate her case with medical records or medical opinion. See id. at 1279 (citing 42 U.S.C. § 300aa-13(a)(1)). Medical records are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. Cucuras, 993 F.2d at 1528. Additionally, "petitioners must proffer trustworthy testimony from experts who can find support for their theories in medical literature in order to show causation under the preponderance of the evidence standard." LaLonde v. Sec'y of Health & Hum. Servs., 746 F.3d 1334, 1341 (Fed. Cir. 2014).

## V. Analysis

Ms. Smith alleges she developed septic shock, neuropathy, and toxic encephalopathy as a direct consequence of the influenza vaccine she received November 4, 2015. Pet., filed Oct. 25, 2018, at pdf 3-4, ¶¶ 6-7. These different conditions are discussed below. Ms. Smith does not provide a medical theory, a logical sequence of cause and effect between the vaccine and her alleged injuries, or a timeframe in which vaccine causation could be inferred. Therefore, Ms. Smith does not meet any of the elements required by Althen.

### A. Septic Shock

To succeed in proving entitlement to compensation, petitioners must show by preponderant evidence "a medical theory causally connecting the vaccination to the injury." Althen, 418 F.3d at 1278. Ms. Smith has not met her burden of presenting a persuasive medical theory that the flu vaccine caused septic shock. Ms. Smith has failed to present any medical records that contain a causal medical theory. Ms. Smith has also failed to present any expert reports or testimony linking the vaccine to septic shock. Consequently, Ms. Smith has not met her burden under the first prong of Althen.

Ms. Smith is also required to show with preponderant evidence "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. The Federal Circuit has instructed special masters to carefully consider the views of treating physicians. Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). Here, statements from Ms. Smith's treating physicians do not support a logical sequence of cause and effect. Ms. Smith's treating doctors determined that the abdominal abscess

and pulmonary infiltrates that had been drained November 2, 2015 caused Ms. Smith's septic shock. Exhibit 2 at pdf 115-16. Thus, the evidence does not support a finding of a logical sequence of events between the vaccine and Ms. Smith's septic shock.

Finally, Ms. Smith must show by preponderant evidence "a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278. Additionally, "[w]hen a petitioner relies upon proof of causation in fact rather than proof of a Table Injury," as Ms. Smith does here, "a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury." Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992). Although Ms. Smith developed septic shock shortly after the flu vaccine, it is not enough to establish causation. The lack of preponderant evidence regarding the first two Althen prongs would still prevent a finding of vaccine-causation.

For these reasons, Ms. Smith has not shown that she is entitled to compensation for septic shock.

**B. Neuropathy**

The nature of Ms. Smith's neuropathy is not clear. Ms. Smith complained about right thigh pain on November 11, 2015. Exhibit 1 at pdf 649-50. However, other than this mention, the medical records created around this time do not memorialize any complaint about thigh pain.

Assuming that Ms. Smith's pain in her right thigh was a manifestation of a neuropathy, Ms. Smith is required to establish, by preponderant evidence, the Althen factors. However, Ms. Smith presents no medical theory causally connecting the flu vaccine to the neuropathy / right thigh pain. There are no medical records or expert witness testimony that convey a medical theory connecting the vaccine to the neuropathy / right thigh pain. Ms. Smith therefore fails to present a medical theory causally connecting the flu vaccine to neuropathy, as required under the first prong of Althen, 418 F.3d at 1278.

Similarly, the lack of a report from a treating doctor or an expert prevent Ms. Smith from establishing the second Althen prong for her claim that the November 4, 2015 vaccination caused her neuropathy / right thigh pain about which she complained on November 11, 2015.

Lastly, Ms. Smith must show by preponderant evidence "a proximate temporal relationship between vaccination and injury." Id. As mentioned

previously, "a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury." Grant, 956 F.2d at 1148. Ms. Smith experiencing right thigh pain six days after receiving the vaccine in her right arm does not necessarily mean the vaccine caused neuropathy.

Alternatively, Ms. Smith's reference to "neuropathy" might be based upon medical records other than the November 11, 2015 report of thigh pain. In February 2016, Ms. Smith saw Dr. Lorraine Huet-Holm, an internal medicine specialist at Sanford Women's Internal Medicine Clinic. Exhibit 7 at 33. The issue of right leg paresthesias was addressed at the visit. Id. The record notes that Ms. Smith and Dr. Huet-Holm "discussed the possibility of doing [a] MRI of [Ms. Smith's] lumbar spine and nerve condition studies to further evaluate [Ms. Smith's] right leg pain and numbness." Id. There is no further clinical information from this visit.

While the report of "paresthesias" suggests a neurologic injury, a finding that Ms. Smith suffered a neuropathy does not mean that the flu vaccination caused the injury. Ms. Smith bears the burden of presenting a theory explaining how a flu vaccine can cause a neuropathy / paresthesia. Although Dr. Ecklund's January 2018 and May 2018 records list neuropathy as the reported reaction to the flu vaccine, see exhibit 8 at 4, 106, there is no discussion about this notation or how it came to appear in the record.[13] This lack of connection between Ms. Smith's neuropathy and the flu vaccine implicates both the first and second prong of Althen. Althen, 418 F.3d at 1278.

Furthermore, the medical records do not reference paresthesia until four months after the vaccine. Exhibit 7 at 33. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and that the onset of the disease occurred in this period. Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542-43 (2011) (quoting de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008)). Ms. Smith has failed to satisfy the first part of the temporal relationship test under Bazan, requiring her to provide a timeframe for which it is medically acceptable to infer causation, as she provides no expert

[13] Since the "allergies" category appears under the "subjective" section rather than the "objective" section, it is likely that Ms. Smith reported the flu vaccine allergy and neuropathy reaction to Dr. Ecklund. See exhibit 8 at 3-4, 106-07.

testimony as to an acceptable timeframe connecting the vaccine to the neuropathy symptoms.

Consequently, regardless of whether Ms. Smith's neuropathy is understood to refer to her report of thigh pain or paresthesia, she has not established with preponderant evidence that the vaccination caused her to suffer a neuropathy.

### C. Toxic Encephalopathy

At the hospital on November 17, 2015, Ms. Smith presented with an encephalopathy. Exhibit 2 at pdf 39. A treating doctor indicated that "possible etiologies include[d] septic encephalopathy with sources of empyema, aspiration pneumonia, or abdominal abscess or overdose/toxic ingestion." Id. Reflective of this diagnosis, in February 2016, when Ms. Smith was referred by Dr. Susan Assam for outpatient speech and language therapy, Dr. Assam noted "encephalopathy due to infection" as the reason for referral. Exhibit 8 at 59.[14]

Medical records created later suggest a different explanation for Ms. Smith's encephalopathy. In January 2018 and May 2018, Dr. Ecklund noted "influenza vaccines" under the allergen category of Ms. Smith's chart, along with "encephalitis" as the reported reaction. Exhibit 8 at 4, 106. There is no discussion about this notation or how or why it came to appear. Ms. Smith also mentioned to Dr. Ecklund in June 2018, that she saw an unidentified rehab doctor "who felt [that] her encephalopathy was due to a vaccine." Exhibit 7 at 10.

Dr. Ecklund's reports do not carry Ms. Smith's burden. Ms. Smith presents no medical theory causally connecting the flu vaccine to toxic encephalopathy. There are no medical records or expert witness reports that put forth a medical theory causally connecting the vaccine to the encephalopathy. Ms. Smith therefore fails to present a medical theory as required under the first prong of Althen.

Under the second prong of Althen, Ms. Smith must show "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. Here, the evidence shows that the doctors who were treating Ms. Smith close in time to her vaccination looked at other factors, such as an abdominal abscess and/or an infection, as the cause for any

[14] Handwritten on this printed document is "encepillitis," as well as other writing that is mostly illegible. Exhibit 8 at 59. It is not clear who handwrote these things or when they were added to the record.

encephalopathy. See, e.g., exhibit 2 at pdf 39; exhibit 8 at 13, 66. This evidence carries more weight than the record created by Dr. Ecklund years later.

Like Ms. Smith's claims regarding septic shock and neuropathy, Ms. Smith seems to rely upon the temporal sequence in which she received the vaccination and then developed an encephalopathy. However, as previously stated, "a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury." Grant, 956 F.2d at 1148. Just because Ms. Smith developed encephalopathy shortly after receiving the flu vaccine is not enough to satisfy causation without the other two prongs of Althen also satisfied. Nonetheless, Ms. Smith has failed to satisfy the first part of the temporal relationship test under Bazan, requiring her to provide a timeframe for which it is medically acceptable to infer causation, as she provides no expert testimony as to an acceptable timeframe connecting the vaccine to encephalopathy. Without this timeframe Ms. Smith fails the second part of the Bazan test, requiring her to show that the injury occurred within the medically accepted timeframe of when the vaccine was administered, as we have no medical standard to compare the timing of the vaccine to when the encephalopathy started.

## VI. Conclusion

The volume of medical records shows that Ms. Smith has suffered various maladies over the years for which she deserves sympathy and compassion. She has also represented herself ably in the gathering of medical records.

However, the medical records do not contain persuasive proof that a treating doctor linked her vaccination to any problem. Ms. Smith has not filled this gap by obtaining a report from an expert. Accordingly, Ms. Smith has not demonstrated with preponderant evidence that she is entitled to compensation.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. For information about motions for review, including the deadline for any motion for review, the parties may consult the Vaccine Rules, which are found on the court's website.

**IT IS SO ORDERED**.

s/Christian J. Moran
Christian J. Moran
Special Master